

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)	
)	
Inventor: William P. Van Antwerp)	Examiner: Bradley James Osinski
)	
Serial No.: 10/616,784)	Group Art Unit: 3767
)	
Filed: July 10, 2003)	Appeal No.: _____
)	

Title: METHODS AND COMPOSITIONS FOR THE INHIBITION OF BIOFILMS ON
MEDICAL DEVICES

REPLY BRIEF OF APPELLANTS

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR §41.41, Appellants hereby submit this Reply Brief in response to the Final Office Action dated September 19, 2009 and the Examiner's Answer dated June 7, 2010.

Please charge any additional fees or credit any overpayments to Deposit Account No. 50-0494 of Gates & Cooper LLP.

.

I. REAL PARTY IN INTEREST

The real party in interest is Medtronic MiniMed, Inc., the assignee of the present application.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences for the above-referenced patent application.

III. STATUS OF CLAIMS

The Application as filed included claims 1-35. During prosecution of the instant Application, claim 1 was amended, claims 2 and 10-35 were cancelled and claims 36-41 were added. Claims 1, 3-9 and 36-41 are pending in the application.

Claims 1, 3-6, 8, 9 and 37-41 were rejected under 35 U.S.C. §103(a) as being obvious in view of Gu et al., World Journal of Microbiology and Biotechnology (Gu) and Steinberg et al., Biodegradation (Steinberg), and these rejections are being appealed.

Claim 7 was rejected under 35 U.S.C. §103(a) as being obvious in view of Gu, Steinberg and Schrier et al., U.S. Patent 6,197,598 (Schrier), and this rejection is being appealed.

Claim 36 was rejected under 35 U.S.C. §103(a) as being obvious in view of Gu, Steinberg and Cioanta et al., U.S. Publication 2002/0082556 (Cioanta).

IV. STATUS OF AMENDMENTS

No amendments to the claims have been made subsequent to the final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Briefly, Appellants' invention, as recited in independent claims 1 and 38, is generally directed to a medical device having a surface coated with a composition comprising a lectin. In this invention, the lectin is selected for its ability to bind to a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device in order to enhance attachment of the microorganism to the composition comprising the lectin. The lectin is disposed within a biodegradable polymer composition that can slough away from the surface of the medical device

when the lectin is bound to the compound produced by a microorganism. The material properties of the lectin (i.e. the ability to promote microbial adhesion) in combination with the material properties of the polymer composition (i.e. the ability to slough away from the medical device) function to inhibit formation of a biofilm on the surface of the medical device.

Referring to the specification by page and line number for the disclosure of the subject matter recited in independent claims 1 and 38, see original claims 1, 3 and 20 at page 39-40, and paragraph [0103]. Referring to the specification by page and line number for the disclosure of the subject matter recited in dependent claims 3-9, 36, 37, and 39-41, see original claims 3-9 at pages 39-40, and paragraph [0103]-[0104].

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1, 3-6, 8, 9 and 37-41 are unpatentable under 35 U.S.C. §103(a) as being rendered obvious by Gu and Steinberg.

Whether claim 7 is unpatentable under 35 U.S.C. §103(a) as being rendered obvious by Gu, Steinberg and Schrier.

Whether claim 36 is unpatentable under 35 U.S.C. §103(a) as being rendered obvious by Gu, Steinberg and Cioanta.

VII. ARGUMENT

The Appeal Brief dated March 17, 2010 provides a detailed analysis showing why those of skill in this art would not agree with the Patent Office's rejection to claims 1, 3-9 and 36-41 under 35 U.S.C. §103(a). This Reply Brief provides a brief reply to the Patent Office's response to Appellant's arguments that is made on pages 6 and 7 the Examiner's Answer dated June 7, 2010. In particular, on page 6 of the Reply Brief, the Patent Office asserts that "one of ordinary skill reading the entirety of Gu would be led to the device of Appellant". Appellant respectfully disagrees for the following reasons.

As noted for example in *KSR v. Teleflex*, 550 U.S. 398, 127 S. Ct. 1727 (2007), in determinations of obviousness under 35 U.S.C. §103(a), there must be some motivation to combine references. M.P.E.P. 2144 notes that prior art used in such determinations of obviousness must be

viewed “as a whole”, including those portions that lead away from the claimed invention (see, e.g. *In re Langer*, 465 F.2d 896, 175 USPQ 169 (CCPA 1972); and *Gore & Assoc. Inc. v. Garlock Inc.* 220 USPQ 303 (Fed. Cir. 1983). In this context, the only disclosure in Gu that the Patent Office can point to in an attempt to support this rejection is as follows: “Lectins are highly specific in blocking or enhancing adhesion of bacteria on surface and, in comparison, the glycoconjugates in the bacterial exopolysaccharides are not yet known for their role in the adhesion and deadhesion process”. This single statement at page 177 of Gu is the only text in this article that mentions the existence of lectins that can enhance the adhesion of bacteria. The Gu disclosure fails to teach or suggest any use whatsoever for lectins having adhesive properties, **much less** their use as recited in Appellant’s claims. In contrast however, the Gu article teaches the use of lectins to **block** bacterial adhesion on medical devices at least 16 times throughout this disclosure (i.e. the *opposite* of what is recited in Appellants’ claims).

The Patent Office’s technical analysis of Gu fails to comply with the provisions of patent law because this analysis does not view the disclosure in Gu “as a whole”. In particular, the Patent Office’s rejection focuses on a single statement in Gu relating to the diverse features of different lectins, while disregarding Gu’s at least 16 specific statements pertaining to coating devices with lectins selected to block adhesion, statements that lead artisans in a direction divergent from the path that was taken by the Applicant. Consequently, one of skill in the art would not interpret Gough as the Patent Office does in order to support the instant rejection under 35 U.S.C. §103(a).

In addition, as noted for example in M.P.E.P. § 2143.01(IV), there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. See, e.g. *In re Kahn*, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). In the instant rejection under 35 U.S.C. §103(a), a single general statement in Gu in combination with observations that growing microbial colonies are known to shed some materials as they grow (e.g. as noted in Steinberg) is not sufficient to provide a rationale underpinning sufficient to establish a prima facie case of obviousness. See, e.g. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). For this additional reason, Appellants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

In summary, because those of skill in this technology would not agree with the Patent Office’s assertion that Gu discloses a catheter coated with lectins capable of binding microorganisms

and further because the combinations/modifications of Gu and Steinberg that are argued by the Patent Office would in fact render the Gu invention unsatisfactory for its intended purpose (as well as change the principle of operation of the lectins of the Gu invention), the Patent Office has failed to meet the threshold for a finding of obviousness under 35 U.S.C. §103(a). For these reasons, a withdrawal of all rejections under 35 U.S.C. §103(a) that are predicated on combinations of Gu and Steinberg is respectfully requested.

C. Conclusion

In light of the above arguments and those submitted with the Appeal Brief dated June 7, 2010, Appellants respectfully submit that the cited references do not anticipate nor render obvious the claimed invention. More specifically, Appellants' claims recite novel physical features which patentably distinguish over any and all references under 35 U.S.C. §§ 102 and 103. As a result, a decision by the Board of Patent Appeals and Interferences reversing the Examiner and directing allowance of the pending claims in the subject application is respectfully solicited.

Respectfully submitted,

GATES & COOPER LLP

Attorneys for Applicant(s)

Howard Hughes Center
6701 Center Drive West, Suite 1050
Los Angeles, California 90045
(310) 641-8797

Date: August 6, 2010

By: /William J. Wood/
Name: William J. Wood
Reg. No.: 42,236

WJW/

G&C 130.62-US-01

APPENDIX

1. (PREVIOUSLY PRESENTED) A medical device having a surface coated with a composition comprising a lectin, wherein:
 - (a) the medical device includes a metallic material;
 - (b) the lectin binds a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device so as to enhance attachment of the microorganism to the composition comprising the lectin; and
 - (c) the lectin is disposed within a biodegradable polymer composition that can slough away from the surface of the medical device when the lectin is bound to the compound produced by a microorganism,
so as to inhibit formation of a biofilm on the surface of the medical device.
2. (CANCELLED)
3. (ORIGINAL) The medical device of claim 2, wherein the biodegradable polymer is a biocompatible polymer that degrades at a controllable rate within an in vivo environment.
4. (ORIGINAL) The medical device of claim 1, wherein the composition further comprises at least one agent that inhibits the growth of the microorganism.
5. (ORIGINAL) The medical device of claim 4, wherein the agent is an antibiotic or an antifungal agent.
6. (ORIGINAL) The medical device of claim 1, wherein the lectin binds to a compound produced by a microorganism selected from the group consisting of *Pseudomonas aeruginosa*, *Streptococcus pneumoniae*, *Streptococcus viridans*, *Haemophilus influenzae*, *Escherichia coli*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Candida albicans*.

7. (ORIGINAL) The medical device of claim 1, wherein the lectin is wheat germ agglutinin or concanavalin A.

8. (ORIGINAL) The medical device of claim 1, wherein the device is implantable.

9. (ORIGINAL) The medical device of claim 8, wherein the device comprises a drug delivery pump, a pacemaker, a cochlear implant, a shunt, a catheter or a cannula.

10-35. (CANCELLED)

36. (PREVIOUSLY PRESENTED) The medical device of claim 1, wherein the metallic material is titanium or stainless steel.

37. (PREVIOUSLY PRESENTED) The medical device of claim 1, wherein the medical device further includes a biostable polymeric material.

38. (PREVIOUSLY PRESENTED) A medical device having a surface coated with a composition comprising a lectin, wherein:

(a) the surface of the medical device includes a biostable polymeric material;

(b) the lectin binds a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device so as to enhance attachment of the microorganism to the composition comprising the lectin; and

(c) the lectin is disposed within a biodegradable polymer composition that can slough away from the biostable polymeric material when the lectin is bound to the compound produced by a microorganism,

so as to inhibit formation of a biofilm on the surface of the medical device.

39. (PREVIOUSLY PRESENTED) The medical device of claim 38, wherein the biostable polymeric material comprises polytetrafluoroethylene.

40. (PREVIOUSLY PRESENTED) The medical device of claim 38, wherein the medical device further includes a metallic material.

41. (PREVIOUSLY PRESENTED) The medical device of claim 1 or claim 38, wherein the composition comprising the lectin is disposed on a region of the device having a mechanical structure that is compatible with the adherence of microorganisms.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.